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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,048	03/15/2001	Mario Carlone	53130/29870	7289

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EXAMINER
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MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/811,048	<b>Applicant(s)</b> CARLONE, MARIO	
	<b>Examiner</b> Ashwin Mehta	<b>Art Unit</b> 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5 and 20 is/are allowed.
- 6) ☒ Claim(s) 6-12, 15, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 13, 14, 16, 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to claim 18 is withdrawn in light of the claim amendment.
3. The rejections of claims 1-11 and 18-20 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, are withdrawn in light of the claim amendments, and assurance that the ATCC accession number in which corn seed designated G3601 was deposited will be inserted into the claims at time of allowance.
4. The rejection of claims 1-20 under 35 U.S.C. 112, 1<sup>st</sup> paragraph, for lack of enablement, is withdrawn, in light of the assurance that the ATCC accession number in which corn seed designated G3601 was deposited will be inserted into the claims at time of allowance.
5. The rejection of claims 6-11 and 14 under 35 U.S.C. 102/103 is withdrawn upon further consideration.

### ***Claim Objections***

6. Claims 13, 14, 16, and 17 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See

MPEP § 608.01(n). Claims 13 and 16 are dependent on two different claims. Claims 14 and 17 are included in this rejection as they are dependent on claims 13 and 16, respectively.

Accordingly, the claims have not been further treated on the merits.

***Claim Rejections - 35 USC § 112***

7. Claims 12 and 15 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed May 14, 2003. Applicant traverses the rejection in the paper filed September 15, 2003.

Applicant's arguments have been fully considered but were not found persuasive.

Applicant argues that "some" of claims 12, 13, 15, and 16 have been amended (response, page 2, 3<sup>rd</sup> full paragraph). However, claims 12 and 15 remain indefinite. The claims are dependent on the plant of claim 2, which is not transgenic and which do not comprise any mutated genes. Further, the process of introducing the transgene or mutant gene indicated in the claim will not result in a plant that is otherwise genotypically G3601. The progeny of a cross between G3601 and another plant will not yield G3601. The metes and bounds of the claims as written are not clear.

8. Claims 6-11, 15, 18, and 19 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention, for the reasons of record stated in the Office action mailed 14 May 2003 under item 4. Applicant traverses the rejection in the paper received 22 September 2003. Applicant's arguments have been fully considered but were not found persuasive.

Applicant argues that techniques such as microsatellites and RFLPs are tools that can be used in breeding, and that the use of markers to identify the parentage of plants used for breeding has long been known and practiced in the art (response, page 3, 2<sup>nd</sup> full paragraph). However, the specification does not describe any such microsatellites, RFLPs, or any other marker.

Applicant argues that Table 2 presents isozyme data of the inbred (paragraph bridging pages 3-4). However, it is not clear if these markers appear in other corn plants. Further, table 2 presents electrophoresis results. The sequences of the markers themselves are not described. Applicants argue that the Examiner is requiring that the hybrids be described by morphological and physiological characteristics, but that this is not needed to identify if a hybrid has the inbred in its parentage (response, paragraph bridging pages 3-4). The Examiner is not requiring Applicant to describe the claimed invention in any specific manner. However, the marker data provided in the specification is not sufficiently described such that one can use it to identify a hybrid as having inbred G3601 as one of its parents. Reasons were detailed in the last Office action.

Applicants argue that running a fingerprint of the genetic material of the plant of the deposited seed with one's own chosen marker set does not require undue experimentation, and will relate to other marker information gathered on other inbreds (response, page 4, 1<sup>st</sup> full paragraph). However, the question of whether experimentation is undue is not the issue, as this a written description rejection.

Applicants argue that the claimed hybrids have 50% of the genetic material of the claimed inbred, that a fingerprint of the inbred is a simple procedure to run, and that comparison with the fingerprint with a hybrid can easily identify its parentage (page 4, 2<sup>nd</sup> full paragraph). However, again, the fingerprint data must be described by the specification. The first paragraph of page 5 of Applicant's response also states that a patent specification must describe the claimed invention. Data collected by one skilled in the art that is not described in the specification does not satisfy the written description requirement.

Applicant cites J.E.M. Ag Supply, Inc. v. Pioneer Hi-bred Intl., Inc., for a patent protects for an inbred corn line protects the seeds and plants of the inbred and hybrids produced using the inbred (response, page 5, 2<sup>nd</sup> full paragraph). However, the issue in that decision concerned utility, not written description, and therefore is not analogous to the instant rejection. The statement pointed out by Applicants was not referring to the requirements for written description.

Applicant also argues that claims have been amended to reflect the type of mutated gene and transgene that is introduced, and assert that support for the language is found in the specification in the first paragraph after the last table (response, page 5, 3<sup>rd</sup> full paragraph). However, the specification does not describe all mutated genes that confer herbicide resistance genes, and does not state that "AE" refers to "amylose extender".

9. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to inbred corn plant G3601 wherein the plant has at least one gene introduced into the plant by crossing with another plant which comprises at least one mutant gene, wherein the mutant gene is selected from a group that includes "amylose extender (AE)." However, the specification does not literally describe "AE" as referring to amylose extender. The recitation is therefore **NEW MATTER**, and must be removed from the claim.

10. Claims 12 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn towards a corn plant produced by inbred corn seed designated G3601, wherein the plant has at least one transgenic gene introduced into the plant by crossing with another plant that has the transgene, or wherein the plant has at least one mutant gene introduced by crossing with another plant that has the mutant gene.

The claims indicate that the plants are obtained by one cross. However, a plant that is G3601, except for the presence of the introduced gene, cannot be recovered by the indicated cross. Rather, the recovered plant will have lost many of the G3601 genes as a result of the cross. The progeny of the cross will inherit only half of the genetic material of G3601. Undue experimentation would be required by one skilled in the art to recover plant G3601, wherein the plant has at least one transgene or mutant gene, from a cross that involves mating G3601 with another variety of corn plant. The claimed plant cannot be recovered from the process as indicated in the claims. Given the breadth of the claims, unpredictability of the prior art, and

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lack of guidance of the specification, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

### *Summary*

11. Claims 1-5 and 20 are allowed. Claims 13, 14, 16, 17 are objected, and claims 6-12, 15, 18, and 19 remain rejected.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### *Contact Information*

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can



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normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

December 29, 2003



Ashwin D. Mehta, Ph.D.

Primary Examiner

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